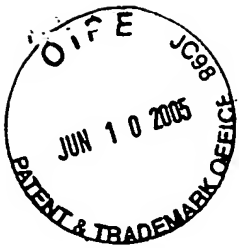


PCT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of :
 Eiji MATSUURA : Docket No. 2005_0348A
 Serial No. 10/526,494 : Group Art Unit **Not Yet Assigned**
 Filed March 4, 2005 : Examiner **Not Yet Assigned**

METHOD OF MEASURING OXIDIZED
 LDL/BETA2-GLYCOPROTEIN I COMPLEX
 OCCURRING IN THE LIVING BODY
 [Corresponding to PCT/JP2003/011388
 Filed September 5, 2003]

THE COMMISSIONER IS AUTHORIZED
 TO CHARGE ANY DEFICIENCY IN THE
 FEES FOR THIS PAPER TO DEPOSIT
 ACCOUNT NO. 23-0975

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

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Sir:

Pursuant to the provisions of 37 CFR 1.56, 1.97 and 1.98, Applicants request consideration of the reference listed on attached form PTO-1449 and any additional information identified below in paragraph 3. A legible copy of each reference listed on the Form PTO-1449 is enclosed, except a copy is not provided for:

- ☒ each U.S. Patent and U.S. Patent application publication;
- ☐ each reference previously cited in the international application PCT/_____; and/or
- ☐ each reference previously cited in prior parent application Serial No. _____.

1a. ☒ This Information Disclosure Statement is submitted:

within three months of the filing date (or of entry into the National Stage) of the above-entitled application, **or**

before the mailing of a first Office Action on the merits or the mailing of a first Office Action after the filing of an RCE,

and thus no certification and/or fee is required.

1b. ☐ This Information Disclosure Statement is submitted

after the events of above paragraph 1a and prior to the mailing date of a final Office Action or a Notice of Allowance or an action which otherwise closes prosecution in the application, and thus:

(1) ☐ the certification of paragraph 2 below is provided, **or**

(2) ☐ the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

1c. ☐ This Information Disclosure Statement is submitted:

after the mailing date of a final Office Action or Notice of Allowance or action which otherwise closes prosecution in the application, and prior to payment of the issue fee, and thus:

the certification of paragraph 2 below is provided, and

the fee of \$180.00 specified in 37 CFR 1.17(p) is enclosed.

2. It is hereby certified

- a. ☐ that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Statement, or
- b. ☐ that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of the Statement.

3. ☐ Consideration of the following list of additional information (including any copending or abandoned U.S. application, prior uses and/or sales, etc.) is requested.
4. For each non-English language reference listed on the attached form PTO-1449, reference is made to:
- a. ☐ a full or partial English language translation submitted herewith,
 - b. ☐ a foreign patent office search report (in the English language) submitted herewith,
 - c. ☐ the concise explanation contained in the specification of the present application at page,
 - d. ☐ the concise explanation set forth in the attached English language abstract,
 - e. ☐ the concise explanation set forth below or on a separate sheet attached to the reference:
5. ☐ A foreign patent office search report citing one or more of the references is enclosed.
6. ☐ Statement Under 37 CFR 1.704(d)

Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign Patent Office in a counterpart application, and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Respectfully submitted,

Eiji MATSUURA

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June 10, 2005

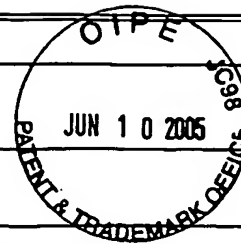
FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)

Date Submitted to PTO: June 10, 2005

ATTY DOCKET NO.
2005_0348ASERIAL NO.
10/526,494APPLICANT
Eiji MATSUURAFILING DATE
March 4, 2005

GROUP



U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,900,359	5/1999	Matsuura et al.			
	AB						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	AC						
	AD						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	AE	K. Kobayashi et al., "A specific ligand for β_2 -glycoprotein I mediates autoantibody-dependent uptake of oxidized low density lipoprotein by macrophages", Journal of Lipid Research, Vol. 42, pp. 697-709, 2001.					
	AF	D. Steinberg et al., "Modification of Low-Density Lipoprotein that Increase its Atherogenicity", The New England Journal of Medicine, Vol. 320, No. 14, pp. 915-924, April 6, 1989.					
	AG	H. C. Boyd et al., "Direct Evidence for a Protein Recognized by a Monoclonal Antibody against Oxidatively Modified LDL in Atherosclerotic Lesions from a Watanabe Heritable Hyperlipidemic Rabbit", American Journal of Pathology, Vol. 135, No. 5, pp. 815-825, November 1989.					
	AH	Y. Nagano et al., "High density lipoprotein loses its effect to stimulate efflux of cholesterol from foam cells after oxidative modification", Proc. Natl. Acad. Sci., Vol. 88, pp. 6457-6461, August 1991.					
	AI	M. Chang et al., "C-reactive protein binds to both oxidized LDL and apoptotic cells through recognition of a common ligand: Phosphorylcholine of oxidized phospholipids", PNAS, Vol. 99, No. 20, pp. 13043-13048, October 1, 2002.					
	AJ	H. Kamido et al., "Lipid ester-bound aldehydes among copper-catalyzed peroxidation products of human plasma lipoproteins", Journal of Lipid Research, Vol. 36, pp. 1876-1886, 1995.					
	AK	G. Hoppe et al., "Oxidation products of cholesteryl linoleate are resistant to hydrolysis in macrophages, form complexes with proteins, and are present in human atherosclerotic lesions", Journal of Lipid Research, Vol. 38, pp. 1347-1360, 1997.					
	AL	H. Kamido et al., "Identification of cholesterol-bound aldehydes in copper-oxidized low density lipoprotein", FEBS LETTERS, Vol. 304, No. 2 & 3, pp. 269-272, June 1992.					

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

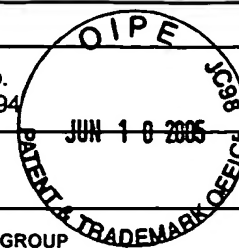
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	BB						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	BC	J. Hulthe et al., "Relationship between C-reactive protein and intima-media thickness in the carotid and femoral arteries and to antibodies against oxidized low-density lipoprotein in healthy men: the atherosclerosis and insulin resistance (AIR) study", Clinical Science, Vol. 100, pp. 371-378, 2001.
	BD	M. Ryan et al., "Antibodies to oxidized lipoproteins and their relationship to myocardial infarction", Q J. Med, Vol. 91, pp. 411-415, 1998.
	BC	C. Monaco et al., "Autoantibodies against oxidized low density lipoproteins in patient with stable angina, unstable angina or peripheral vascular disease", European Heart Journal, Vol. 22, pp. 1572-1577, 2001.
	BF	E. Matsuura et al., "Anticardiolipin Antibodies Recognize β_2 -Glycoprotein I Structure Altered by Interacting with an Oxygen Modified Solid Phase Surface", J. Exp. Med., Vol. 179, pp. 457-462, February 1994.
	BI	B. Bouma et al., "Adhesion mechanism of human β_2 -glycoprotein I to phospholipids based on its crystal structure", The EMBO Journal, Vol. 18, No. 19, pp. 5166-5174, 1999.
	BH	M. Hoshino et al., "Identification of the Phospholipid-binding Site of Human β_2 -Glycoprotein I Domain V by Heteronuclear Magnetic Resonance", J. Mol. Biol., Vol. 304, pp. 927-939, 1998.
	BI	D. Hong et al., "Flexible Loop of β_2 -Glycoprotein I Domain V Specifically Interacts with Hydrophobic Ligands", Biochemistry, Vol. 40, pp. 8092-8100, 2001.
	BJ	Y. Hasunuma et al., "Involvement of β_2 -glycoprotein I and anticardiolipin antibodies in oxidatively modified low-density lipoprotein uptake by macrophages", Clin. Exp. Immunol., Vol. 107, pp. 569-573, 1997.
	BK	L. Kritharides et al., "A Method for Defining the Stages of Low-Density Lipoprotein Oxidation by the Separation of Cholesterol-and Cholesteryl Ester-Oxidation Products using HPLC", Analytical Biochemistry, Vol. 213, pp. 79-89, 1993.
	BL	J. George et al., "Induction of Early Atherosclerosis in LDL-Receptor-Deficient Mice Immunized with β_2 -Glycoprotein I", Basic Science Reports, pp. 1108-1114, September 15, 1998.

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DATE CONSIDERED

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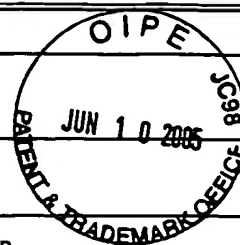
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FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	CB						

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

	CC	J. George et al., "Immunolocalization of β_2 -Glycoprotein I (Apolipoprotein H) to Human Atherosclerotic Plaques" Basic Rapid Communication, pp. 2227-2229, May 4, 1999.
	CD	E. Matsuura et al., "Proteolytic cleavage of β_2 -glycoprotein I: reduction of antigenicity and the structural relationship", International Immunology, Vol. 12, No. 8, pp. 1183-1192, 2000.
	CC	P. Holvoet et al., "Oxidized LDL and Malondialdehyde-Modified LDL in Patients with Acute Coronary Syndromes and Stable Coronary Artery Disease", American Heart Association, pp. 1487-1494, October 13, 1998.
	CF	K. Ichikawa et al., "A Chimeric Antibody with the Human $\gamma 1$ Constant Region as a Putative Standard for Assays to Detect IgG β_2 -Glycoprotein I-Dependent Anticardiolipin and Anti- β_2 -Glycoprotein I Antibodies", Arthritis & Rheumatism, Vol. 42, No. 11, pp. 2461-2470, November 1999.
	CG	A. Ambrozic et al., "Anti- β_2 -glycoprotein I antibodies in children with atopic dermatitis", International Immunology, Vol. 14, No. 7, pp. 823-830, 2002.
	CH	Q. Liu et al., " ω -Carboxyl variants of 7-ketocholesteryl esters are ligands for β_2 -glycoprotein I and mediate antibody-dependent uptake of oxidized LDL by macrophages", Journal of Lipid Research, Vol. 43, pp. 1486-1494, 2002.
	CK	G. M. Iverson et al., "The Orientation of β_2 GPI on the Plate is Important for the Binding of Anti- β_2 GPI Autoantibodies by ELISA", Journal of Autoimmunity, Vol. 18, pp. 289-297, 2002.
	CJ	E. Matsuura et al., "Anti- β_2 -Glycoprotein I Autoantibodies and Atherosclerosis", Intern. Rev. Immunol., Vol. 21, pp. 51-66, 2002.
	CK	S. Yasuda et al., " β_2 -glycoprotein I deficiency: prevalence, genetic background and effects on plasma lipoprotein metabolism and hemostasis", Atherosclerosis, Vol. 152, pp. 337-346, 2000.
	CL	J. George et al., "Oxidized low-density lipoprotein (Ox-LDL) but not LDL aggravates the manifestations of experimental antiphospholipid syndrome (APS)", Clin. Exp. Immunol., Vol. 108, pp. 227-233, 1997.

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DATE CONSIDERED